



News Flash – Since May 29, 2007, Medicare Fiscal Intermediaries, as well as Part B CIGNA Idaho and Tennessee, have been validating National Provider Identifiers (NPIs) and Legacy Provider Identifier pairs submitted on claims against the Medicare NPI Crosswalk. Between the period of September 3, 2007 and October 29, 2007, all other Part B carriers and DME MACS will begin to turn on edits to validate the NPI/Legacy pairs submitted on claims. If the pair is not found on the Medicare NPI crosswalk, the claim will reject. Medicare contractors have been instructed to inform providers at a minimum of seven days prior to turning on the edits to validate the NPI/Legacy pairs against the Crosswalk.

MLN Matters Number: MM5719

Related Change Request (CR) #: 5719

Related CR Release Date: September 7, 2007

Effective Date: July 9, 2007

Related CR Transmittal #: R74NCD

Implementation Date: October 9, 2007

Medicare Clinical Trial Policy (CTP)

Provider Types Affected

All physicians, providers, and suppliers who submit claims related to clinical trials to Medicare contractors (carriers, Medicare Administrative Contractors (A/B MACs), durable medical equipment Medicare Administrative Contractors (DME MACs), fiscal intermediaries (FIs), and regional home health intermediaries (RHHIs))

Provider Action Needed



STOP – Impact to You

This article is based on Change Request (CR) 5719, which implements two changes to the 2000 clinical trial policy by: (1) modifying for clarity the language describing coverage of an investigational item/service in the context of a clinical trial, and, (2) adopting coverage with evidence development (CED). The remainder of the 2000 clinical trials policy continues without change.

Disclaimer

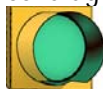
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CR 5719 states that for items and services furnished on and after July 9, 2007, the routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial. The investigational item or service itself is excluded, *unless otherwise covered outside of the clinical trial*.



CAUTION – What You Need to Know

In addition, the National Coverage Determination (NCD) is revised to add coverage with evidence development (CED). CED is for items and services in clinical research trials for which there is some evidence of significant medical benefit, but for which there is insufficient evidence to support a “reasonable and necessary” determination. CED is determined through the NCD process, and conditional upon meeting standards of patient safety and clinical evidence, items and services not otherwise covered would be considered “reasonable and necessary” in the context of a clinical trial. Coverage determined under CED is implemented via subsequent NCDs, CRs, and *MLN Matters* articles specific to the coverage issue.



GO – What You Need to Do

Make certain your billing staffs are aware of these changes. Medicare contractors will adjust claims processed prior to the implementation date of this change if you bring such claims to their attention.

Background

On June 7, 2000, the President of the United States issued an executive memorandum directing the Secretary of Health and Human Services to “explicitly authorize [Medicare] payment for routine patient care costs and costs due to medical complications associated with participation in clinical trials.” In keeping with the President's directive, the Centers for Medicare & Medicaid Services (CMS) engaged in defining the routine costs of clinical trials and identifying the clinical trials for which payment for such routine costs should be made. On September 19, 2000, CMS implemented its initial Clinical Trial Policy through the NCD process. On July 10, 2006, CMS opened a reconsideration of its NCD on clinical trials in the NCD Manual, section 310.1. CR5719 communicates the findings resulting from that analysis.

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Additional Information

To see the official instruction (CR5719) issued to your Medicare FI, carrier, DME MAC, RHHI or A/B MAC, visit

<http://www.cms.hhs.gov/transmittals/downloads/R74NCD.pdf> on the CMS website.

If you have questions, please contact your Medicare FI, carrier, DME MAC, RHHI or A/B MAC at their toll-free number, which may be found at:

<http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.

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